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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,587	08/19/2003	Samuel Bogoch	9425/468031	2933
23838	7590	09/24/2007		
KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700 WASHINGTON, DC 20005			EXAMINER EMCH, GREGORY S	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/642,587	Applicant(s) BOGOCH ET AL.	
	Examiner Gregory S. Emch	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 15 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15 and 24-27 is/are allowed.
- 6) ☒ Claim(s) 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 07 August 2007 has been entered.

Response to Amendment

Claims 13, 15 and 24-27 are pending in the instant application.

Claims 13, 15 and 24-27 are under examination in the instant office action.

Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicants' response and withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The obviousness-type double patenting rejection of claim 13 as being unpatentable over claims 12-14 of U.S. Patent No. 4,298,590 is maintained for reasons of record and as set forth below.

The obviousness-type double patenting rejection of claim 13 as being unpatentable over claims 7-11, 20 and 21 of U.S. Patent No. 4,486,538 is maintained for reasons of record and as set forth below.

In the reply filed 07 August 2007, Applicants assert that the instant specification does not teach, suggest or imply antibodies to SEQ ID NO: 2 (or obvious variants thereof) were inherent in the cited prior art and Applicants' specification makes clear that antibodies to SEQ ID NO: 2 are a novel and nonobvious species of the genus of antimalignin antibodies. Applicants further assert that the skilled artisan would understand that antimalignin antibodies disclosed in the prior art were not necessarily directed at the SEQ ID NO: 2 epitope. Applicants further assert that any antibody alleged in the cited prior art that is produced *in vivo* does not meet each element of claim 13, which requires a "purified" and "monoclonal" antibody. Applicants assert that the prior art references submitted in the response filed on 26 June 2007 establishes that the skilled artisan would understand that: "(1) an intact *in vivo* protein such as malignin may contain several distinct epitopes against which antibodies to all epitopes would not be expected to be produced using the methods of the cited prior art; (2) each malignin epitope may have more than one antibody formed against it, none of which would necessarily be produced using the techniques of the cited art; (3) each antibody to a malignin epitope may have some (not complete) cross-affinity for another epitope, which is nevertheless unknown without further investigation; (4) knowing the specific amino acid sequence of any one of several epitopes provides the advantage of identifying a specific antibody to a specific epitope from among the genus of antibodies to any epitope on the intact protein (this advantage is seen in Applicants' disclosure concerning antibodies to synthetic SEQ ID NO :2); (5) absent specific disclosure of the specific sequence of SEQ ID NO: 2, it is not possible for one of skill in the art to necessarily

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produce an antibody to SEQ ID NO: 2 using only the intact malignin protein disclosed in the cited prior art." Thus, Applicants conclude that the cited prior art patents did not necessarily disclose an antibody of claim 13 and that the Examiner has provided no evidence to refute this understanding. Applicants allege that the Examiner's statement taken from the instant specification, i.e., from p.12, lines 6-9, which states "It has now been determined that the two longer sequences represent immunologic epitopes responsible for recognition by the body's immune system and the resultant production *in vivo* of the specific antibody, anti-aglyco 10B (antimalignin antibody)," is inappropriate because the skilled artisan would immediately recognize that Applicants' statement is directed to the *in vivo* production of antibodies to the malignin oncoprotein. Further, Applicants allege that the skilled artisan "would immediately recognize Applicants' statement to be directed to the production of the genus of any antibody against any epitope on the entire malignin oncoprotein for the purpose of establishing that native aglyco substances are in fact responsible for the immune response observed in human cancer and not for the purpose of establishing that antibodies to SEQ ID NO: 2 were present in the prior art." Applicants allege that the instant Example 6 teaches that "antimalignin antibodies" are a genus.

Applicants' arguments have been fully considered and are not found persuasive.

Once a reference teaching product appearing to be substantially identical is made the basis of a rejection, and the examiner presents evidence or reasoning tending to show inherency, the burden shifts to Applicant to show an unobvious difference (see MPEP 2112 (V)). Upon reading the disclosure of the '538 patent as well as the

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disclosure of the instant application, the skilled artisan would necessarily conclude that the antimalignin antibodies disclosed in the prior art were directed at the SEQ ID NO: 2 epitope.

The disclosure of the '538 patent reveals that when an animal is inoculated with the malignin protein, two distinct antibodies are produced. For example, the abstract of the '538 patent teaches, "Described herein is the production of two products which are distinct **species** of anti-malignin antibody, and the production of three artificially produced species of cell each of which has the distinguishing characteristic of manufacturing either one or both species of anti-malignin antibody" [Emphasis added]. Col.1, lines 20-28 reiterates the information provided in the abstract and col.1, line 29 – col.2, line 3 teaches that the production of monoclonal antibodies (through hybridoma techniques for example) is routine in the art and that the instant two species of antibodies can be produced in this way. Col.2, lines 21-68 teaches, "From the earliest production by the inventor of anti-malignin antibody (Issued U.S. Pat. Nos. 4,195,017 and 4,196,186) two constituent species of the antibody were recognized: (1) Fast Target-attaching-globulin (F-TAG), which combined rapidly in vitro, within 10 minutes, with its specific immobilized antigen malignin; and (2) Slow Target-attaching-globulin (S-TAG), which combined slowly in vitro, within 2 hours, with its specific immobilized antigen malignin...The present invention is a marked improvement since it describes the production of a unique novel cell line which produces only the S-TAG species, one cell line which produces only the F-TAG species, and one cell line which produces both species...In the present invention, it has been found that the **single species of**

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monoclonal antibody product produced here for the first time **S-TAG**, Monoclonal Anti-Malignin Antibody--Slow (MAMA-S), attaches preferentially to cancer cells but does not destroy them. Also, the **single species of monoclonal antibody** product here produced for the first time for **F-TAG**, Monoclonal Anti-Malignin Antibody--Fast (MAMA-F) attaches preferentially to cancer cells but does not destroy them." [Emphasis added].

As stated previously, starting at p.22 of the instant specification, it is taught that SEQ ID NO: 2 was injected subcutaneously into rabbits. Following subsequent booster injections, the animals were bled to determine "antimalignin antibody concentration," in which the antibody was immunoabsorbed against intact immobilized "aglycoprotein 10B (malignin)." The results show that both the "fast-binding antibody" (F-TAG, i.e., the species of antibody taught by the '538 patent) and the "slow-binding antibody" (S-TAG i.e., the species of antibody taught by the '538 patent) increase significantly over baseline levels (pre-injection levels). On pp.23-24, it is taught, "This increase in F-TAG before the increase in S-TAG is the same as that seen *in vitro* when isolated lymphocytes in tissue culture are induced by intact Aglyco 10B to produce antimalignin antibody (Cancer Detection and Prevention 12:313-320, 1988). The repetition of this phenomenon with synthetic peptide epitopes injected into rabbits is further confirmation of the fact that the synthetic peptides reproduce exactly the production and release into serum of antimalignin antibody" [Emphasis added].

The Examiner agrees with Applicants' assertion that the skilled artisan "would understand that Applicants' data was directed to demonstrating SEQ ID NO: 1 and SEQ ID NO: 2 were epitopes of malignin." The Examiner also agrees that "One of skill in the

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art would not understand Applicants' data to be directed to proving that all antimalignin antibodies of the genus are in fact the same species" and that "the skilled artisan would immediately understand that different antibodies are necessarily produced to different epitopes." However, the prior art refers to F-TAG and S-TAG as "single species of antimalignin" and the instant application teaches that inoculation of animals with SEQ ID NO: 2 results in production of these "species." The Examiner understands that production of polyclonal antibodies through an immunogenic challenge is different than production of a purified monoclonal antibody. However, the '538 patent teaches production of purified monoclonal antibodies from monoclonal antibodies, which are deemed "single species" of monoclonal antibodies (F-TAG and S-TAG, the same terms used to describe antibodies raised by inoculation with SEQ ID NO: 2). Thus, upon reading the prior art and the instant disclosure, the artisan would necessarily conclude that the antimalignin antibodies disclosed in the prior art were directed at the SEQ ID NO: 2 epitope. The USPTO does not have the resources or facilities to determine if the prior art antibodies in fact bind to instant SEQ ID NO: 2. The examiner has set forth a prima facie case of inherency, and has provided sound scientific reasoning as to why the prior art antibodies would necessarily bind to the now-disclosed peptide. After setting forth a prima facie case of inherency, the burden shifts to applicant to provide evidence that the products now claimed are patentably distinct from those in the prior art; see MPEP § 2112(V). Applicants' submitted prior art references do not provide the requisite evidence to overcome the instant rejections, since the evidence set forth in the

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'538 patent and in the instant application outweighs the evidence set forth in said references.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claim 13 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,486,538 to Bogoch is maintained for reasons of record and as set forth above for the obviousness-type double patenting rejections.

Conclusion

Claims 15 and 24-27 are allowable.

Claim 13 is rejected.

It is noted that the Examiner contacted Applicants' representative, Richard Ward on 12 September 2007 in an effort to advance prosecution of the instant application. The Examiner proposed canceling claim 13 in order to advance the application to issue, and Applicants declined.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the

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grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory S. Emch/

Gregory S. Emch, Ph.D.
Patent Examiner
Art Unit 1649
13 September 2007

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646